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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

In Re Bard IVC Filters Products Liability Litigation	No. MD-15-02641-PHX-DGC **PLAINTIFFS' SEPARATE STATEMENT OF FACTS IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT REGARDING PREEMPTION**

Plaintiffs submit this Separate Statement of Facts in Support of their Opposition to Defendants' Motion for Summary Regarding Preemption. Plaintiffs contend that there is no genuine issue to be tried as to the following facts:

1. Devices that receive pre-market approval (PMA) are considered "approved" by the FDA. Second Supplemental Report of David Kessler, attached hereto as Exhibit 1.D at ¶ 13.[1]

2. Devices found by the FDA to be substantially equivalent to a predicate device are said to be "cleared" by the FDA. Ex. 1.D at ¶ 15.

3. FDA's 510(k) clearance process determines if the device is substantially equivalent to a predicate device already marketed. Ex. 1.D at ¶ 15; Affidavit Ramon Rossi Lopez, attached hereto as Exhibit 2, at Ex. A at 9-10.

4. FDA determination in the 510(k) process that a device is substantially equivalent to a predicate device is not a finding that the device is safe and effective for its intended conditions of use. Ex. 1.D at ¶ 18.

5. FDA determination in the 510(k) process that a device is substantially equivalent to a predicate device it is a determination that the device is as safe and effective as the predicate device based on the information submitted by the manufacturer. Ex. 1.D at ¶ 18.

6. Bard received a 510(k) clearance letter for each of its Inferior Vena Cava filters ("IVC filters"). For each of the filters, the FDA:

> [D]etermined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration….If your device is classified (see above) into either class II (Special Controls) or class III (PMA) it may be subject to additional controls. … Please be advised

[1] This report was incorporated by reference in the Declaration of David Kessler (August 28, 2017), attached hereto as Exhibit 1.A, at ¶ 5.

> that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act…

Bard SOF Ex. A ("Carr Decl.") at Exs. 12, 23, 67, 103, 114, 119, 124; Bard SOF Ex. B ("VanVleet Decl.") at Exs. 31, 79; *see also* Ex. 1.D at ¶ 21.

7. Each of Bard's IVC Filters marketed as permanent devices with optional retrieval received a substantial equivalence determination on the following dates:

a. Recovery – November 27, 2002 (permanent)

b. Recovery – July 25, 2003 (permanent with optional retrievability)

c. G2 – August 29, 2005 (permanent)

d. G2 – January 15, 2008 (permanent with optional retrievability optional retrievability)

e. G2 Express – July 30, 2008 (permanent with optional retrievability)

f. G2X/Express – October 31, 2008 (permanent with optional retrievability)

g. Eclipse – June 18, 2010 (permanent with optional retrievability)

h. Meridian – August 24, 2011 (permanent with optional retrievability)

i. Denali Filters – May 15, 2013 (permanent with optional retrievability)

Carr Decl. at Exs. 12, 23, 67, 103, 114, 119, 124; VanVleet Decl. at Exs. 31, 79.

8. Bard made additional 510(k) submissions to FDA, but those submissions did not alter any of the filters themselves, but rather altered brochures or modified its delivery systems or which do not remain in the body after the filter is deployed.

a. K052578 – G2 – Sep. 19, 2005 – Change to the delivery system

b. K062887 – G2 – Sep. 25, 2006 – Change to the delivery system

c. K080668 – G2 Express – Aug. 12, 2008 – Change to delivery system

d. K101431 – Eclipse – May 10, 2010 – Change to patient brochure

e. K112497 – Meridian – Oct. 24, 2011 - Changes to the delivery system

Carr Decl. at Exs. 89, 99, 115, 125; VanVleet Decl. at Ex. 32.

9. The SMDA of 1990 allowed the FDA to go from performance standards to "special controls" which were less administratively burdensome on the agency

because, prior to 1990, the MDA of 1976 required that agency promulgate regulations setting out performance standards for each Class II device which the agency was criticized for failing to do. Ex. 1.D at ¶¶ 34-35.

10. FDA clearance letters applicable to Bard's devices specifically differentiate between class II products subject to special controls and class III PMA approved products. Carr Decl. at Exs. 12, 23, 67, 103, 114, 119, 124; VanVleet Decl. at Exs. 31, 79.

11. When a device is cleared to be marketed through the 510(k) process this does not reflect a determination by the FDA that the device is safe and effective. Ex. 2 at Ex. B at 57:19-58:17; Ex. 1.D at ¶ 1.

12. The FDA may require additional information in an effort to determine whether the device is substantially equivalent to a predicate device. Ex. 1.D. at ¶ 21.

13. The clinical data that is requested in the 510(k) process is aimed at answering the question of whether the device is substantially equivalent to the predicate. Such clinical data does not serve as an independent determination of the safety and effectiveness of the device. Ex. 1 at ¶ 21; Ex. 2 at Ex. C at 6.

14. Language in Bard's Instructions for Use ("Label" or "IFU") cleared by FDA was not the result of specific language promulgated by Congress or FDA, but rather were negotiations with FDA reviewers where they "proposed labeling changes", would "recommend some modifications, and where Bard discussed FDA's proposals and provided agreement if it chose to implement. VanVleet Decl. at Ex. 30 (BPVEFILTER-08-00077841-42); Carr Decl. at Ex 14 (BPV-17-01-00055232); Ex. 2 at Ex. D at 92:1-4.

15. A 510(k) application must demonstrate that the device is substantially equivalent to a device that (1) was legally in commercial distribution in the US before May 28, 1976; or (2) has been determined by FDA to be substantially equivalent. 510(k) premarket applications can "piggyback" by demonstrating substantial equivalence to a device that has been found substantially equivalent. This practice has

led to significant controversy and concern that many important devices are not being reviewed for safety and effectiveness. Ex. 1.D at ¶ 17.

16. The FDA deems a device substantially equivalent if, in comparison to a predicate, it:

- has the same intended use as the predicate; **and**
- has the same technological characteristics as the predicate; **or**
- has the same intended use as the predicate; **and**
- has different technological characteristics and the information submitted to FDA:
  - does not raise new questions of safety and effectiveness; **and**
  - demonstrates that the device is at least as safe and effective as the legally marketed device.

Ex. 1.D at ¶ 16.

17. Bard's IVC filters were cleared to market based on substantial equivalence to a previous Bard filter also cleared via the 510(k) process. Ex. 1.D at ¶ 24; Ex. 2 at Ex. E.

18. Nothing in Bard's 510(k) submissions were required by the FDA beyond what was necessary for Bard to establish substantial equivalence under the 510(k) clearance process. Ex. 1.D at ¶ 24.

19. The special controls assigned to IVC filter devices in general are codified at 21 C.F.R. § 870.3375 and include:

a. ISO 10993 Biological Evaluation of Medical Devices Part I: Evaluation and Testing
b. Updated 510(k) Sterility Review Guidance K90-1; Guidance for Industry and FDA (August 30, 2002)
c. FDA Guidance for Cardiovascular Intravascular Filter 510(k) Submissions (Nov. 26, 1999) ("1999 Guidance").

21 C.F.R. § 870.3375.

20. Updated 510(k) Sterility Review Guidance K90-1; Guidance for Industry and FDA (August 30, 2002) is not IVC filter-specific. It addresses all implants. Ex. 2 at Ex. F at 33:25-34:3.

21. Updated 510(k) Sterility Review Guidance K90-1; Guidance for Industry and FDA (August 30, 2002) addresses sterility and is not IVC filter-specific. *Id*. at 33:9-33:21.

22. ISO 10993 Biological Evaluation of Medical Devices Part I: Evaluation and Testing is not device-specific, it applies to all devices. *Id*. at 32:19-33:2.

23. The 1999 FDA Guidance for Cardiovascular Intravascular Filter 510(k) Submissions (Nov. 26, 1999) ("1999 Guidance") was issued prior to any of Bard's optionally retrievable IVC filters received FDA clearance (i.e., Recovery, all G2 filters, Eclipse, Meridian, and Denali). Carr Decl. at Exs. 12, 23, 67, 103, 114, 119, 124; VanVleet Decl. at Exs. 31, 79; Ex. 2 at Ex. U.

24. The 1999 Guidance is guidance from FDA, not a requirement. Ex. 2 at Ex. F at 34:4-7.

25. The 1999 Guidance lists the content one should consider submitting with a 510(k) submission for all vena cava filters, not just retrievable devices. *Id*. at 34:9-11.

26. The content of the 1999 Guidance is not specific to Bard's IVC filters. *Id*. at 53:25-54:25.

27. The content of the 1999 Guidance is not specific to retrievable filters. *Id*.

28. Performance standards referenced in all of Bard's 510(k) applications for its IVC filters were set by Bard; none were set by FDA. Carr Decl. at Exs. 12, 23, 67, 103, 114, 119, 124; VanVleet Decl. at Exs. 31, 79.

29. The content of the 1999 Guidance does not require or recommend specific performance standards for any IVC filter, including Bard's optionally retrievable permanent filters. Ex. 1.D at ¶ 38.

30. The content of the 1999 Guidance does not require or recommend patient registries for any IVC filter, including for Bard's optionally retrievable permanent filters. *Id*. at ¶ 38.

31. The content of the 1999 Guidance does not require or recommend specific tracking requirements for any IVC filter, including for Bard's optionally retrievable permanent filters. *Id*.

32. The content of the 1999 Guidance does not require or recommend specific design controls for any IVC filter, including for Bard's optionally retrievable permanent filters. *Id*.

33. The content of the 1999 Guidance does not require or recommend any specific clinical or pre-clinical trial parameters or testing methods. *Id*.

34. The content of the 1999 Guidance does not did not include any specific labeling language for fracture, migration, perforation, tilt, inability to retrieve, embedding, thrombosis or occlusion of the IVC. *Id*.

35. Notifications from FDA during the 510(k) process that a manufacturer's failure to respond to FDA requests within 30 days is not specific to IVC filters. Ex. 2 at Ex. F at 44:20- 45:5.

36. Bard maintains control over its 510(k) submissions and can withdraw them at their prerogative as it did with 510(k) submission number K090392 which was submitted on February 13, 2009, seeking a prophylactic indication and voluntarily withdrawn on April 29, 2009. Ex. 2 at Ex G (BPV-17-01-00262213-14); Ex. H (BPV-01-01525227).

37. None of the special controls for IVC filter devices codified at 21 C.F.R. § 870.3375 are specific to the Recovery filter. Ex. 2 at Ex. F at 53:25-54:25.

38. None of the special controls for IVC filter devices codified at 21 C.F.R. § 870.3375 are specific to the G2, G2X or G2 Express filters. *Id*.

39. None of the special controls for IVC filter devices codified at 21 C.F.R. § 870.3375 are specific to the Eclipse filter. *Id*.

40. None of the special controls for IVC filter devices codified at 21 C.F.R. § 870.3375 are specific to the Meridian filter. *Id*.

41. None of the special controls for IVC filter devices codified at 21 C.F.R. § 870.3375 are specific to the Denali filter. *Id*.

42. None of Bard's filters have undergone PMA review, including all predicate devices to the filters at issue. Ex. 1.D at ¶ 23.

43. Bard never performed biocompatibility testing specifically on its Recovery filter and therefore did not submit biocompatibility testing results with its 510(k) applications for its Recovery filters; Bard submitted biocompatibility testing data from its previous 510(k) application for the Simon Nitinol Filter (SNF) K894703 cleared on 4/20/90. Carr Decl. at Ex. 9 at 16 (BPV-17-01-00057770).

44. When FDA requested additional testing data for Bard's filters, Bard acknowledges that providing such data is to support substantial equivalence to a predicate device. Carr Decl. at Ex. 6 at BPVE-17-01-00058035; Carr Decl. at Ex. 113 at BPV-17-01-00117260.

45. No clinical study was ever conducted for Bard's first retrievable filter, the Recovery. Carr Decl. at Ex. 15 at BPV-17-01-00054093.

46. Performance data submitted by Bard as part of its safety and effectiveness summary to FDA indicates that compliance with the 1999 Guidance shows substantial equivalence. Carr Decl. at Ex. 6 at BPV-17-01-00058034-35.

47. There are no design controls promulgated by Congress in the FDC Act applicable to Bard's IVC filters or any other IVC filters under 21 C.F.R. § 820.30. Carr Decl. at Exs. 12, 23, 67, 103, 114, 119, 124; VanVleet Decl. at Exs. 31, 79, Carr Decl. at Ex. 14 at BPV-17-0100054956; Carr Decl. at Ex. 54 at BPV-17-01-00125442.

48. There are no performance standards promulgated by Congress or FDA specific to Bard's IVC filters or any other IVC filters. Carr Decl. at Ex. 14 at BPV-17-0100054956; 21 C.F.R. §§1010-1050; Ex. 1.D at ¶¶ 38, 45.

49. Upon issuance, a finding of substantial equivalence for each of Bard's filters, FDA distinguished Bard's filters regarding regulatory action to take based on the difference between whether it had been 510(k) cleared or PMA approved. Carr Decl. at Exs. 12, 23, 67, 103, 114, 119, 124; VanVleet Decl. at Exs. 31, 79.

50. Bard describes labeling that FDA has reviewed with regard to the Recovery filter's IFU as its "suggested changes" not requirements. Carr. Decl. at Ex. 28 at BPV-17-01-00029512.

51. Bard engaged in three clinical studies involving human subjects: 1) the Murray Asch Study, 2) the EVEREST study, and 3) the Denali study. These studies were designed to evaluate placement and retrievability only. Carr Decl. Ex. 6 at BPV-17-01-00057981-57986; Ex. 2 at Ex. I at 19:2-20:11; Ex. 2 at Ex. W (BPVE-502d-00000013-019); Ex. 2 at Ex. J.

52. The Asch Study, Everest, and Denali Trial were not well-controlled studies as defined by 21 C.F.R. § 860.7 because they lacked any proper control group for comparison. Ex. 1.D at ¶ 26.

53. None of Bard's clinical studies met the 2-year clinical follow up for adverse events including migration, filter fracture, filter tilting, filter fracture embolization, perforation, IVC occlusion/thrombosis, worsening or new onset deep vein thrombosis and pulmonary embolism as set out by the agency in its February 28, 2013, letters regarding PRESERVE. *Id*.

54. FDA FOIA productions indicate that FDA was interested in seeing comparative failure rates between Bard's filters and its competitors' filters. Carr Decl. at Ex. 27 at FDA_PRODUCTION_00001026.

55. Bard did not provide competitive failure rate data comparing failure rates between Bard's filters and its competitors' filters. Ex. 2 at Ex. K at BPV-17-01-000098737-738.

56. Given the opportunity to substantiate the claim that Bard submitted competitive failure rate data to the FDA, Bard Declarant Robert Carr could only

provide examples of descriptions Bard employees gave FDA of MAUDE data, not actual test data. Ex. 2 at Ex. F at 64:3-66:20; Exs. 2 at Ex. L1 and L2.

57. As early as June 12, 1998, internal meeting notes with Dr. John Kaufman and Robert Carr show that a preliminary sheep study showed the Recovery filter was associated with penetrations that were a "perhaps product killing problem." Ex. 2 at Ex. M at BPV-17-01-00072616.

58. These June 12, 1998, meeting notes were not submitted to FDA for review in the 510(k) pre-notification submission for the Recovery filter. Carr Decl. Exs. 1, 6, 14.

59. The same June 12, 1998, internal meeting notes with Robert Carr present indicates that the results causes the investigator to be "troubled by the degree to which the arms protruded beyond the IVC wall" and "bothered by the apparent penetration of the filter elements." Ex. 2 at Ex. M at BPV-17-01-00072615.

60. An important note of the June 12, 1998, internal meeting minutes related to the Recovery filter's testing in sheep included a statement that "the perception of many clinicians would be strongly negative. We took from this comment that we may need to have sized devices for appearance's sake even if it is not required to reduce the likelihood of penetration. We need additional marketing input." *Id*.

61. Boston Biomedical Associates ("BBA") served as the contract research organization acting as medical monitor of the EVEREST clinical trial evaluating the retrievability of the G2 device. Ex. 2 at Ex. N at BBA-00013699-13715.

62. Minutes of the Medical Monitor Adjudication Minutes dated August 28, 2006, and October 26, 2006, indicate that Dr. Kris Kandarpa acting as medical monitor expressed concern over the number of device observations he noted it was not in his charter to stop the study but expressed that Bard may want to consider a re-design of the device based on this information. *Id*.; *see also id.* at BBA-00012803.

63. These Medical Monitor Adjudication Minutes dated October 26, 2006, were not shared with the FDA. Carr Decl. at Exs. 12, 23, 67, 103, 114, 119, 124; Bard VanVleet Decl. at Exs. 31, 79.

64. Minutes of the Medical Monitor Adjudication Minutes dated December 8, 2006, indicate that Dr. Kandarpa reviewed draft table for a clinical report related to the EVEREST study with particular attention paid to the device observations. The Device Observation Tables outlined all reported device observations including migration, tilt, penetration as well as filter movements. Ex. 2 at Ex. O at BBA-00013300-13309.

65. Dr. Kandarpa's concern arose to the level of questioning whether FDA should clear the G2 device being examined in the EVEREST trial. Ex. 2 at Ex. P at BBA-00013151-13158.

66. Bard did not share Dr. Kandarpa's concerns with the FDA. Bard SSOF Carr Decl. Exs. 12, 23, 67, 103, 114, 119, 124; VanVleet Decl. at Exs. 31, 79; Ex. 2 at Ex. D at 48:11-49:25; 52:19-53:3.

67. In previous cases regarding Bard's IVC filters, Plaintiffs have moved *in limine* to exclude almost all evidence of the facts Bard has attached to its current moving papers in order to avoid undue delay of trials. Ex. 2 at Ex. Q.

68. Exhibit R to Exhibit 2 is a chart prepared by counsel outlining the nature of Bard's communications with the FDA concerning its filters that are the subject of this action.

69. The 1997 Guidance document relating to contact lens solution differs dramatically in size, content, rigor and flexibility from the 1999 Guidance for IVC filters. *Compare* Ex. 2 at Ex. U *with* Ex. 2 at Ex. Y.

70. Bard's employees state internally that SNF and competitor filters are safer alternatives to Bard's optionally retrievable filters. Ex. 2 at Exs. S, V (BPVE-01-00280224-280225) and X (BPVE-01-01019821-9825).

71. On July 13, 2015, the FDA sent a "Warning Letter" to Bard for, in addition to other violations, improperly evaluating and reporting adverse event complaints related to its IVC filters. Ex. 2 at Ex. T.

72. None of the predicates for any of Bard's optionally retrievable IVC filters, or the predicates for those predicates, ever received FDA approval via the PMA process. Ex. 1.D at ¶ 23.

73. Bard, in arguing against summary judgment on its government rules defense in *Austin v. Bard*, claimed that whether safety and efficacy underlie the 510(k) process creates a genuine issue of fact precluding summary judgment. Ex. 2 at Ex. Z at 41:12-49:4.

RESPECTFULLY SUBMITTED this 1st day of September, 2017.

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I hereby certify that on this 1st day of September, 2017, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Gay Mennuti